

## **REMARKS**

### **Entry of Amendment**

As Applicants are filing a RCE herewith, this amendment should be entered and considered by the Examiner at this time.

Applicants have the following comments in support of this amendment.

### **I. Claim Amendments - Reference To The Disclosure**

In order to further clarify the claimed sanitizing compositions of the present application, Applicants are amending independent Claims 1 and 9. In particular, these claims have been amended to clarify that the claimed compositions are directed to liquid sanitizing compositions having principal components at certain preferred concentrations.

More specifically, the specification of the present application at, for example, paragraph [0029] reports a preferred concentration of biocide (volatile alcohol) of 30-70% w/v and a non-volatile antimicrobial agent concentration of 0.001-0.1% w/v. Example test preparation containing 60-70% alcohol and 0.04% triclosan (non-volatile antimicrobial agent) are described, for example, in paragraph [0041], while a similar test preparation containing 0.01% triclosan is described in paragraph [0044]. Paragraph [0045] shows that the test preparation composition of paragraph [0044] retains activity upon dilution by a factor of 10 or greater. Thus, these paragraphs support the presently claimed range of biocide (volatile alcohol) of 30-70% w/v and of non-volatile antimicrobial agent of less than or equal to 0.01% w/v.

As explained in the present application, the claimed sanitizing composition achieves an

unanticipated synergistic bactericidal activity. See e.g. paragraphs [0037], [0038], [0043], [0045], [0057] and [0060], along with Applicants' assay data shown in Tables 1 and 4 in the specification of the present application. These passages clearly show that the claimed compositions have bactericidal properties and achieve an unexpected synergistic bactericidal result in comparison to conventional preparations, such as "Brand A" and "Brand B" commercial hand sanitizing preparations.

Therefore, the amendments to the claims have not added any new matter and are clearly supported by the original application as filed. Hence, it is respectfully requested that these amendments be entered and considered at this time.

## **II. Claim Rejections - 35 U.S.C. §103**

### **A. Scholtz**

In the Final Rejection, the Examiner continues to reject Claims 1, 5-7, 9, 10 and 13-15 under 35 U.S.C. §103(a) as being unpatentable over Scholz (U.S. 5,908,619). This rejection is respectfully traversed.

While Applicants traverse this rejection, in order to advance the prosecution of this application, Applicants are amending Claims 1 and 9, as explained above, to clarify that the claimed invention is directed to certain liquid sanitizing compositions having particular preferred, and previously unpredicted, ranges of principal components. As explained herein and shown in the specification of the present application, the claimed ranges produced unexpected beneficial results. In contrast, there is no disclosure or suggestion in Scholz of the composition of amended Claims 1 and 9.

More specifically, on p. 3 of the Final Rejection, the Examiner argues that Scholtz teaches that chlorhexidine and triclosan...are equivalent and that “since Scholtz teaches that chlorhexidine is present in an amount of about 0.05%-5.0%, one of ordinary skill would contemplate the addition of its equivalent, triclosan, in those same amounts.” Even if Applicants agreed with this position by the Examiner, it is clear that such reasoning would not lead one of skill in the art to utilize an antimicrobial agent at far lower concentrations, as taught in the specification of the present application and presently claimed in the amended claims.

In particular, Applicants’ presently claimed upper limit of 0.01% is a factor of 5 lower than the lowest limit taught by Scholtz (to the extent that any level of any antimicrobial agent is taught, specifically only for chlorhexidine), while Applicants’ claimed lower limit of 0.001% is a factor of 50 lower than the lowest limit taught by Scholtz. Furthermore, the claimed range of amended Claims 1 and 9 is at least a factor of 20 lower than the range of 0.2% to 2% triclosan taught in the “Guideline for Hand Hygiene in Health-Care Settings,” Morbidity and Mortality Weekly Report (e.g., MMWR/RR-16, first cited in paragraph [0002] of the specification, and cited in detail in paragraph [0016] in the present application). There is no reason why one of ordinary skill in the art would be led to pursue the dramatically lower levels of the claimed invention based upon a reading of this art.

Thus, Applicants’ claimed composition is well outside the metes and bounds established by Scholtz or other prior teachings, such as MMWR/RR-16. Further, as explained above, the claimed compositions have bactericidal properties and achieve an unexpected synergistic bactericidal result in comparison to conventional preparations. Furthermore, Scholz appears to teach away from such lower levels and any significant downward extrapolation from the teachings of Scholtz would be contrary to the teaching of Scholtz, as Scholtz clearly states,

“The most preferred antimicrobial is chlorhexidine digluconate (CHG). CHG is preferably present at a concentration of about 0.05-5.0%, more preferably about 0.1-3%, even more preferably about 0.25-2%, and most preferably about 0.5-1%, by weight....” (column17, lines 54-58).

Therefore, any such downward extrapolation in the rejection to arrive at the claimed ranges could only be based upon improper hindsight reconstruction, using Applicants’ teachings and claims as a guide, and in clear contrast to Scholtz’s unambiguously declared logic that “more is better” (i.e., 0.1% is better than 0.05%, 0.25% is better than 0.1%, and 0.5% is better than 0.25%).

Thus, to arrive at Applicants’ claimed invention from the teachings of Scholtz, one of ordinary skill in the art would be required to at least (1) replace “the most preferred antimicrobial” with triclosan and (2) reduce the lowest prescribed concentration of antimicrobial agent by at least a factor of 5, and by at least a factor of 50 from the lowest “most preferable” level. This would also require a reason to go against the teachings of the MMWR/RR-16, which itself is consistent with the teachings of Scholtz. There, however, was no reason for one skilled in the art to utilize such lower ranges. Instead, Applicants achieved unexpected results from such lower ranges.

For at least these above reasons, independent Claims 1 and 9 are not disclosed or suggested by Scholz, and Claims 1 and 9 and those claims dependent thereon are patentably distinct over Scholz. Accordingly, it is requested that this rejection be withdrawn.

B. Scholtz in view of Luu

The Examiner also continues to reject Claims 1, 5-7, 9, 10 and 13-15 under 35 U.S.C. §103(a) as being unpatentable over Scholz (U.S. 5,908,619) in view of Luu et al. (U.S. 5,871,763). This rejection is also respectfully traversed.

As discussed *supra*, Scholz does not teach nor suggest the amended compositions of Claims 1 and 9.

Further, there is no motivation for one skilled in the art to combine the disclosure in Luu with Scholz to arrive at the claimed invention. Scholz concerns certain topical agents for direct application to the skin as a surgical hand disinfectant or antimicrobial lotion, whereas Luu concerns certain emollient lotions (i.e., moisturizing lotions) adapted for application to solid substrates, such as tissues and other paper or cloth wipes. Other than by identifying a common component of these disparate compositions (triclosan), the Examiner makes no clear case where one of skill in the art would be led to combine these unrelated compositions to arrive at Applicants' claimed compositions. It is evident from the non-overlapping Fields of Search for the two U.S. patents (e.g., 424/402 and 424/404 for Luu vs. 424/78.02 for Scholtz) and U.S. patent classifications (e.g., 424/402 and 424/404 for Luu vs. 424/78.02, 424/78.07, 514/772.4, 514/772.3 and 514/772.6 for Scholtz) that the one of ordinary skill in the art would have been unlikely to make a connection between the two disclosures.

Furthermore, it is important to note that the compositions of Luu are fundamentally unrelated to the compositions of Scholtz. In particular, a key component of Luu's lotion is a fatty alcohol ester or polyvinyl alcohol (i.e., one or more emollients, as made clear in the Abstract and subsequent specification as well as the independent claims); however Luu makes no reference to or suggestion of a volatile alcohol. In contrast, a key component of Scholtz's compositions is a volatile alcohol (i.e., a biocide). Thus, Luu's composition is not even remotely related to Scholtz's compositions (nor to those claimed by the Applicants, which includes a volatile alcohol).

In addition, claims 1 and 22 in Luu specify a substrate comprising an emollient with a

melting temperature of at least 30°C, whereas the volatile alcohols of Scholtz have dramatically lower melting temperatures, such as:

- ethanol, mp = -114°C;
- isopropanol, mp = -89.5°C; and
- n-propanol, mp = -127°C.

Clearly, the volatile alcohols of Scholtz are unrelated to the emollients (fatty alcohol esters or polyvinyl alcohols) of Luu.

However, assuming *arguendo* that a skilled artisan was led to combine these teachings, Luu makes only passing reference to inclusion of “a medicinal agent” in this lotion as one of several “optional ingredients” for the lotion. (column 1, lines 6-13 and column 9, lines 24, 59). This contrasts with the central role such components play in the compositions of Scholtz (and those of the present application). The lowest specified limit for any such generic medicinal agent is stated as “about 0.01%” or higher, and more preferably “about 0.05%” or higher (column 9, lines 30-31). Triclosan is disclosed as a member of a lengthy list of “medicinal agents” that includes “medicines, antipathogenic agents, antimicrobial agents, antibacterial agents, antiviral agents, disinfectants, analgesics....” (column 9, lines 25-28). Luu does not provide any data on formulations actually containing triclosan nor any guidance on selection of concentration within this generic range.

Thus, the teachings of Luu are unrelated to those of Scholtz, and any relevance to Scholtz with possible regard to Applicants’ claimed compositions can only result from hindsight reconstruction. It is well understood that there must be reason for one skilled in the art to combine references to arrive at the claimed invention. See KSR International Co. v. Teleflex Inc., 550 USPQ2d 1385 (2007). It is not merely enough to note that all the elements of a claimed invention are known. As

noted in KSR when explaining why a reason to combine references is important, “inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” In this case, there is no reason to selectively combine a minuscule portion of Luu’s disclosure of certain emollient compositions for treatment of tissues with other portions of Scholz’s disclosure to arrive at the claimed liquid bactericidal compositions of the present application. Rather, such a combination involving picking and choosing select teachings based on the claims of the present application is improper hindsight reconstruction and any rejection based thereon should be reversed. See e.g. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

Out of an abundance of caution and in order to advance the prosecution of this application, Applicants have amended Claims 1 and 9 to clarify that the claimed invention is directed to certain liquid sanitizing compositions having particular preferred, and previously unpredicted, ranges of principal components. The range of antimicrobial agent has been specified to avoid superficial overlap with the preferred range specified by Luu so as to render Luu moot. Further, as explained above, the claimed ranges produce an unexpected result.

Therefore, independent Claims 1 and 9 and those claims dependent thereon are not disclosed or suggested by the cited references, and Claims 1 and 9 and those claims dependent thereon are patentably distinct over these references. Accordingly, it is respectfully requested that this rejection be withdrawn.

## **Conclusion**

For at least the above-stated reasons, it is respectfully submitted that the claims of the present

application are in an allowable condition and are patentable over the cited references. Accordingly, it is requested that the application now be allowed.

If any fee should be due for this amendment, please charge our deposit account 23-0920.

Favorable reconsideration is earnestly solicited.

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